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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,044	09/19/2003	Valery Migachyov	1005.1110103	6577
28075	7590	12/14/2004	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC			VENIAMINOV, NIKITA R	
1221 NICOLLET AVENUE			ART UNIT	PAPER NUMBER
SUITE 800				3736
MINNEAPOLIS, MN 55403-2420				

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/666,044	MIGACHYOV, VALERY
	<b>Examiner</b>	<b>Art Unit</b>
	Nikita R Veniaminov	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 20-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 49-62 is/are allowed.
- 6) Claim(s) 20-33 and 35-47 is/are rejected.
- 7) Claim(s) 34 and 48 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/05/2003</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 12/05/2003 was considered by the examiner.

### ***Specification***

2. The disclosure is objected to because of the following informalities:  
The phrase "now is U.S. Patent No. 6,652,448 B2," should be inserted before the phrase "which" on page 1, line4; the phrase "now is a U.S. Patent No. 6,183,413 B1" should be inserted after the phrase "1998"on page 1, line 5. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

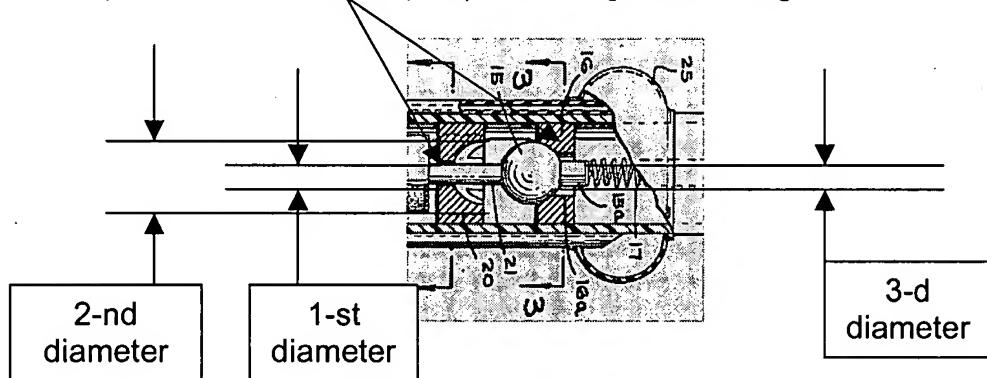
A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 20- 25, 29-33, 35, 38-40 and 44-47** are rejected under 35 U.S.C. 102(b) as being anticipated by Isaacson (US 3,812,841) cited by Applicant. Isaacson ('841) teaches a valve for a bladder control device, comprising:

**Claims 20 and 35 (independent)**

an elongate housing (12) having a proximal end, a distal end (Figures 1 and 2), and a valve lumen (16a) extending therethrough,



said valve lumen (16a) including a first lumen portion defining a first lumen diameter, a second lumen portion distal the first lumen portion defining a second lumen diameter greater than the first lumen diameter, and a third lumen portion distal the second lumen portion defining a third lumen diameter less than the second lumen diameter;

a valve seat (16) disposed within the housing (12);

a stopper (15) disposed within the housing (12) and moveable between a first position engaging the valve seat (16) and a second position disposed distally of the valve seat (16) (Examiner considered "a first position" depicted on Figure 2 at the distal end of the second lumen; and "a second position" depicted on Figure 2 at the distal end of the second lumen), said

stopper being configured to move within the first lumen portion in response to fluidic pressure without allowing fluid to flow through the valve lumen (16a) (Examiner states, that the language "being configured to move.." directed to the intended use of the device, thus does not reflect any structural limitations set forth in the claim); and a spring (17) connected to the stopper (15) to bias the stopper (15) toward the valve seat (16);

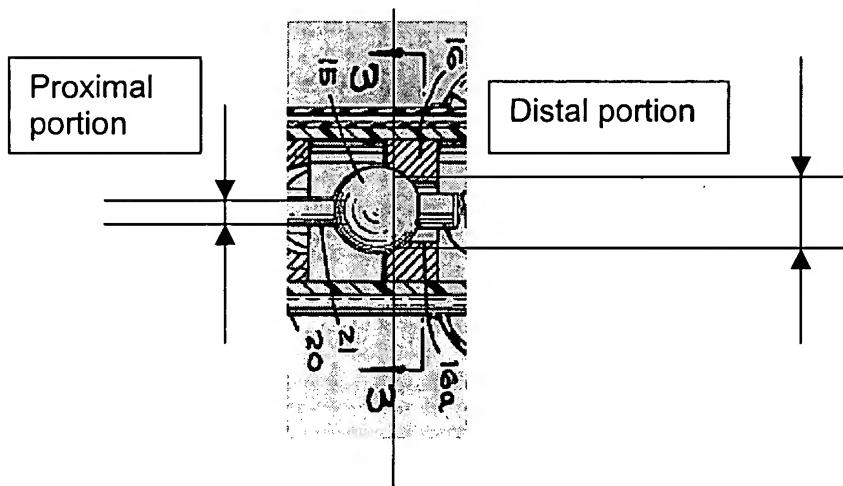
**(elements of Claim 35)** an elongate shaft portion (15a) coupling the spring (17) to the stopper (15);

### **Claim 21**

the valve of claim 20, wherein the stopper (15) includes a proximal portion having a first diameter;

### **Claim 22**

the valve of claim 21, wherein the stopper includes a distal portion having a second diameter greater than said first diameter;



**Claims 23 and 38**

the valve of claim 20 and 35, wherein the valve lumen (16a) tapers along a slope between the second lumen portion and the third lumen portion (Examiner considered that a portion between the second lumen and the valve lumen (16A), where the stopper (15) is contacting the valve seat as tapering as depicted on Figure 2);

**Claims 24 and 39**

the valve of claims 23 and 38, wherein the stopper (15) includes a sloping portion;

**Claims 25 and 40**

the valve of claims 24 and 39, wherein the slope between the second and third lumen portions and the sloping portion of the stopper (15) are configured to create an initial negative pressure within the valve lumen in response to fluid flow (Examiner states, that the slope between the second and third lumen portions of the stopper is capable of creating the initial negative pressure within the valve lumen in response to fluid flow in accordance with the Bernoulli Principle, that as the velocity of a fluid increases, its pressure decreases; and the velocity of the urine flow will increase when the urine starts flow through the third lumen of the valve from the urine bladder, where the pressure is higher than in the valve, into the valve body through the second lumen around the stopper (15), where the pressure is less than in the bladder);

**Claims 29 and 44**

the valve of claims 20 and 35, wherein the spring (17) is a tension spring (column 3, lines 3-4);

**Claims 30 and 45**

the valve of claims 29 and 44, wherein the spring (17) is under greater tension loading when the stopper is in the second position than when the stopper is in the first position (Figure 2 and column 3, lines 3-16);

**Claims 31 and 46**

the valve of claims 20 and 35, wherein the spring (17) includes a helical portion (Examiner considered the coiled spring as a spring, having a helical portion);

**Claims 32 and 47**

the valve of claims 20 and 35, wherein the spring (17) is disposed distally of the stopper (15) (Figure 2);

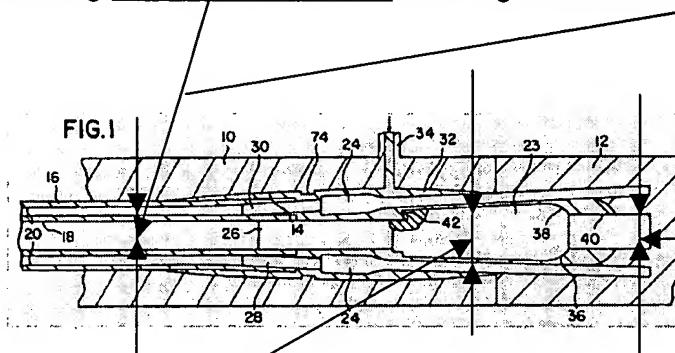
**Claim 33**

the valve of claim 20, further comprising an elongate shaft portion (15a) coupling the spring (17) to the stopper (15).

5. **Claims 20-25, 31, 33, 35-40 and 46** are rejected under 35 U.S.C. 102(e) as being anticipated by Davis (US 5,713,877) cited by Applicant. Davis ('877) teaches a valve for a bladder control device, comprising:

**Claims 20 and 35 (independent)**

an elongate housing (32) having a proximal end, a distal end (Figures 1 and 2), and a valve lumen (18) extending therethrough, said valve lumen (18) including a first lumen portion defining a first lumen diameter,



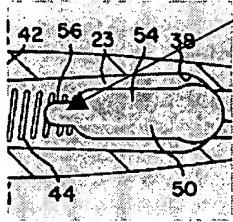
a second lumen portion distal the first lumen portion defining a second lumen diameter greater than the first lumen diameter, and a third lumen portion distal the second lumen portion defining a third lumen diameter less than the second lumen diameter;

a valve seat (38) disposed within the housing (32);

a stopper (50) disposed within the housing (32) and moveable between a first position engaging the valve seat (32) and a second position disposed distally of the valve seat (32) (Examiner considered "a first position" depicted on Figure 2 at the distal end of the second lumen; and "a second position" depicted on Figure 4 at the distal end of the second lumen), said stopper being configured to move within the first lumen portion in response to fluidic pressure without allowing fluid to flow through the valve lumen (40) (Examiner states, that the language "being configured to move.." directed to the intended use of the device, thus does not reflect any structural limitations set forth in the claim);

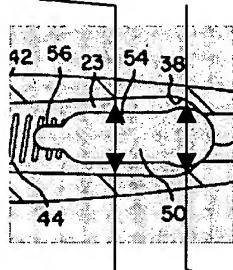
and a spring (44) connected to the stopper (50) to bias the stopper (50) toward the valve seat (38);

**(elements of Claim 35)** an elongate shaft portion coupling the spring (44) to the stopper (50);



### Claims 21 and 36

the valve of claims 20 and 35, wherein the stopper (50) includes a proximal portion having a first diameter;

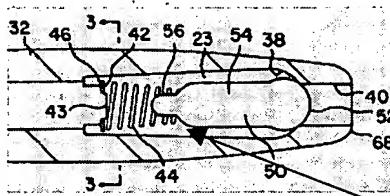


### Claims 22 and 37

the valve of claim 21, wherein the stopper (50) includes a distal portion having a second diameter greater than said first diameter;

**Claims 23 and 38**

the valve of claim 20 and 35, wherein the valve lumen tapers along a slope between the second lumen portion and the third lumen portion (distal portion of the valve housing (32) on Figure 2 between elements 32 and 38);

**Figure 2****Claims 24 and 39**

the valve of claim 23 and 38, wherein the stopper (50) includes a sloping portion;

**Claims 25 and 40**

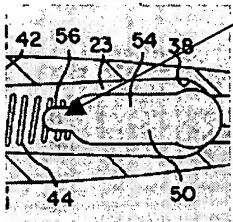
the valve of claim 24 and 39, wherein the slope between the second and third lumen portions (Figure 2 depicted above) and the sloping portion of the stopper (50) are configured to create an initial negative pressure within the valve lumen in response to fluid flow (Examiner states, that the language "configured to..." directed to the intended use of the device, thus does not reflect any structural limitations set forth in the claim);

**Claim 31 and 46**

the valve of claim 20 and 35, wherein the spring (44) includes a helical portion (column 4, line12) (Examiner considered the coiled spring as a spring, having a helical portion);

### Claim 33

the valve of claim 20, further comprising an elongate shaft portion coupling  
the spring (44) to the stopper (50);



### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 26-28 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacson (US 3,812,841) cited by Applicant.**  
Isaacson ('841) teaches a valve for a bladder control device, as described in paragraph 4 above, but the exact dimensions of the housing has not been set forth. In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art to select any suitable dimension for the device, since the claimed sizes are within the generally expected ranges for the size of the urethra. The selection of the exact dimension would be a matter of ordinary engineering design choice.

8. **Claims 26-28 and 41-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (US 5,713,877) cited by Applicant. Davis ('877) teaches a valve for a bladder control device, as described in paragraph 5 above, but the exact dimensions of the housing has not been set forth. In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art to select any suitable dimension for the device, since the claimed sizes are within the generally expected ranges for the size of the urethra. The selection of the exact dimension would be a matter of ordinary engineering design choice.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. **Claims 20-33 and 35-47** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

**claims 1-19** of U.S. Patent No. 6,183,413. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the present application are broader than claims in the patent. Therefore, any apparatus or method meeting the limitations of the patent would necessarily meet those of the claims of the application.

10. **Claims 20-33 and 35-47** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-37** of U.S. Patent No. 6,652,448. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the present application are broader than claims in the patent. Therefore, any apparatus or method meeting the limitations of the patent would necessarily meet those of the claims of the application.

#### ***Allowable Subject Matter***

11. **Claims 49-62** are allowed.
12. **Claims 34 and 48** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
13. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art, either alone or in combination, teaches or suggests a valve for a bladder control device,

wherein a proximal end of an elongate shaft portion being disposed within an internal bore of a stopper.

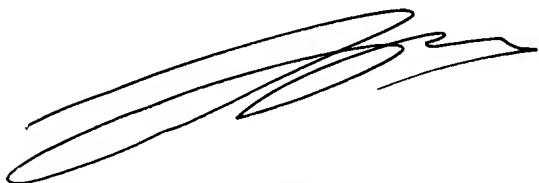
***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Migachyov et al. ('593) ; Kulisz et al. ('916) ; Nishioka et al. ('936); Willard ('060); Kalb et al. ('182); Migachyov ('179); Willard ('967); Pham ('016); Ardito ('314); Kalb et al. ('434); Kalb et al. ('889); Kalb et al. ('353); Chaussy et al. ('312) and Horne, Jr. et al. ('896).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

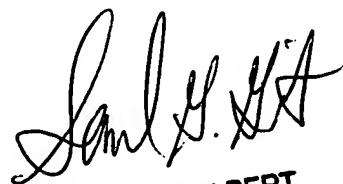
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov  
Examiner  
Art Unit 3736

December 02, 2004.



SAMUEL G. GILBERT  
PRIMARY EXAMINER